

Accelerated Development Pathway I

PA 14-01: CIRM Accelerated Development Pathway

The purpose of PA 14-01 is to identify and accelerate high-potential programs that are funded by CIRM to conduct clinical research using a stem cell-based therapeutic, particularly those that may demonstrate clinical proof concept during, or before, the year 2017. The program will provide selected applicants who are making rapid progress with additional resources and financial support to further accelerate their stem cell-based therapy towards demonstrating evidence of an acceptable safety profile and clinical proof of concept. An applicant team will be asked to propose new, complementary activities that reflect their early progress and which, if conducted concurrently with the on-going funded project, could significantly accelerate and advance their program, yet cannot be pursued without disrupting their original timeline and budget. Under the Accelerated Development Pathway, applicants may propose key clinical or nonclinical development activities, manufacturing changes, or a follow-on clinical trial to demonstrate proof of concept with the funded stem cell-based therapeutic.

Application to PA 14-01 is open only to current CIRM grantees who hold an active Disease Team Research or Therapy Development award, or a Strategic Partnership award (RFA 09-01, RFA 10-05, RFA 12-05, RFA 12-09 or RFA 13-01) that includes funding to conduct a clinical trial.

Please see the PA for full details.

PA 14-01: CIRM Accelerated Development Pathway

Informational Webinar

CIRM conducted a webinar on **March 19, 2014 at 10:00 am** (PDT) to provide information regarding PA14-01 including tips to potential applicants, an overview of the application process and questions from applicants. You can view:

- The Session Recording
- Presentation Slides
- The Q&A document

Application Process

Submission of an application for the CIRM Accelerated Development Pathway PA involves a two-step process. An eligible applicant must first submit a Letter of Intent (LOI) to CIRM following the instructions below. In the second step of the process, eligible applicants will submit a full application. The Principal Investigator and the project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.

LOI Submission Instructions:

The letter of Intent forms will be made available on the CIRM Grants Management Portal

(https://grants.cirm.ca.gov/login/upgrade_browser) the week of March 10th. The Letter of Intent (LOI) must be submitted via the CIRM Grants Management Portal, as follows:

1. Go to the Grants Management Portal (https://grants.cirm.ca.gov/login/upgrade_browser) and log in with your existing CIRM Username and Password. If you do not have a Username, click on the **"New User"** link and follow the instructions to create a CIRM Username and password.
2. After logging in, click on the **"Menu"** tab. Select the link labeled **"Open Programs"**. Under the section labeled **"RFAs and Programs Open for Applications"**, click on the **"Start a Letter of Intent"** link located to the right of the section labeled **"PA 14-01 CIRM Accelerated Development Pathway: Letter of Intent"**.
3. Complete the LOI by following the posted instructions.
4. The **"Done with Letter of Intent"** button becomes enabled when all sections are complete. Select this button to complete your LOI submission. Once this button has been selected, you will no longer be able to make changes to your LOI.
5. To ensure the process is complete, click on the **"Menu"** tab and select "Your Submitted Applications" from the drop down list. Your submission for **"PA 14-01 CIRM Accelerated Development Pathway: Letter of Intent"** should appear in the section titled **"Your**

Submitted Applications".

The LOI must be received by CIRM no later than **5:00 pm (PDT), March 24, 2014** via the CIRM Grants Management Portal. No exceptions to this deadline will be made.

Application Instructions and Forms

Application forms will be available on the CIRM Grants Management Portal (https://grants.cirm.ca.gov/login/upgrade_browser) in mid-March.

Only those applicants that submitted an LOI that was accepted by CIRM may submit an application. Applicants will be notified if their LOI was NOT accepted.

A description of all application components can be found within the PA. To assist in your preparation for the Accelerated Development Pathway application, sample documents of key application components are provided at the end of the PA.

The application for RFA 14-01 consists of at least eight parts:

- Part A – Application Information (web based)
- Part B – Proposal for Accelerated Development Plan (MS Word template)
- Part C – Biographical Sketches for Key Personnel (MS Word template)
- Part D – Activity Based Budget (MS Excel template)
- Part E – FDA Correspondence
- Part F – Clinical Protocol for Funded Clinical Trial
- Part G – Investigator Brochure for Funded Clinical Trial
- Part H – Clinical Protocol for Follow-on Clinical Trial (if applicable)
- Part I – Investigator Brochure for Follow-on Clinical Trial (if applicable)
- Part J – Intellectual Property and Licensing Agreements

All applicable parts of the Application for PA 14-01: CIRM Accelerated Development Pathway must be submitted together and received by CIRM no later than 5:00 pm (PDT), April 28, 2014 via the CIRM Grants Management Portal. It is the applicant's responsibility to meet this deadline. No exceptions will be made.

Schedule of CIRM Deadlines and Reviews	Date
Letters of Intent due	5:00 pm (PDT), March 24, 2014
Applications due	5:00 pm (PDT), April 28, 2014
Supplemental Information due	5:00 pm (PDT), June 5, 2014
Scientific Review of Applications by Grants Working Group (GWG)	Summer 2014
Review and Approval by ICOC	Fall 2014

Contacts

For information about this PA:

Catherine Priest, Ph.D

Science Officer
California Institute for Regenerative Medicine
Email: cpriest@cirm.ca.gov
Phone: (415) 396-9805

For information about the review process:

Gilberto R. Sambrano, Ph.D.
Associate Director, Review
California Institute for Regenerative Medicine
Email: gsambrano@cirm.ca.gov
Phone: (415) 396-9103

ICOC approval:

Sep 10, 2014

Source URL: <https://www.cirm.ca.gov/our-funding/research-rfas/accelerated-development-pathway-i>